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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,232	04/11/2005	Barbara Sambuco	260236US0PCT	7049
22850	7590	09/20/2007		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER HAGHIGHATIAN, MINA	
			ART UNIT	PAPER NUMBER
			1616	
			NOTIFICATION DATE	DELIVERY MODE
			09/20/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/510,232	SAMBUCO ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/21/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Amendments, Remarks and IDS filed on 06/21/07.
Claims 1-18 have been cancelled and new claims 19-44 have been added. Accordingly,
claims **19-44** are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 recites the limitation "The process as claimed in claim 41". There is
insufficient antecedent basis for this limitation in the claim. Claim 41 is drawn to a
"pharmaceutical formulation" and not a process.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that
form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 19-44 are rejected under 35 U.S.C. 102(b) as being anticipated by
Bernini et al (WO 00/25746).**

Bernini et al teach a process for the preparation of suspensions of drug particles for inhalation delivery, said process providing particles of optimized particle size and distribution homogeneously dispersed in the carrier (see abstract). The process is carried out by using a turboemulsifier, optionally followed by a treatment with a high pressure homogenizer. Accordingly, said process includes a first step wherein an aqueous solution which constitutes the carrier is dispersed in a turboemulsifier apparatus. A typical turboemulsifier suitable for the treatment comprises a containment vessel equipped with magnetic stirring and a high potency turbine system which is used for **homogenizing the suspension**. The apparatus can also be fitted with a heating jacket as well as a **vacuum system**. In a second step, one or more micronised active ingredients, obtained after conventional milling, are added to the aqueous phase and dispersed in the same turboemulsifier vessel by applying very high speed (2000-3000 r.p.m for 15 to 30 minutes (see page 2, lines 13-32).

Bernini et al also disclose that the mean diameter of at least 90% of the particles is lower than or equal to 5 micron (page 4, lines 5-7). Suitable drugs include beclomethasone dipropionate. The formulations can be prepared by dispersing the active ingredient in an aqueous solution or in a high-boiling organic solvents, such as alcohols. According to the particle size and particle distribution obtained, they can be used either for pulmonary or nasal delivery (see page 7, lines 2-12). It is also stated that the said formulations for inhalation can be advantageously used in the **treatment of** allergic and/or **respiratory disorders such as asthma**, COPD, etc (page 11, lines 18-22).

The resulting suspension can be directly partitioned under sterile conditions, in plastic single-dose containers, pre-formed and sterilized by suitable treatments or produced in sterile by employing the "blow, fill and seal" technology. Additionally, a process for making therapeutically acceptable micronised BDP sterile as a result of gamma-ray irradiation is disclosed (see page 8, lines 15-25).

Tables 1 and 2 show particle size distribution of beclomethasone dipropionate particles, as measured by Malvern apparatus, in both irradiated and non-irradiated formulations. It is shown that the diameter of 90% of the particles can be less than 8 microns or less than 7 microns, diameter of 50% of the particles can be from 2 to 3.5 micron or from 2.5 to 3 microns.

NOTE: Claim 37 recites a concentration range of 0.01 to 0.1% w/v and claim 42 requires a concentration of 0.04% w/v. Although the said range and amount are not explicitly disclosed by Bernini et al, it is considered that concentration is determined according to the needs of the patient and the capacity of the delivery device as well as other factors.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **19-44** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-9 and 13 of U.S. Patent No. 6,464,958. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are anticipated by the reference claims. In other words all that is recited in instant claims falls within the scope of reference claims. Specifically the process for the preparation of an aqueous suspension to be used in formulations for inhalation recited in the instant claim 2 comprise the same steps and limitations as the process in reference claims. The active agent, excipients, particle size and particle size distribution, as well as turboemulsifier's limitations are the same or very similar.

Claims **19-42** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/538,888 (US 20070140980). Although the conflicting

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claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims. The instant claims and the reference claims are drawn to a process for the preparation of aqueous suspension. The difference is that the reference claims recite the process steps of preparing the suspension by employing the device, while the instant claims recite the process steps of device preparing the suspension. However the process steps and the final products are the same and one of ordinary skill in the art would have been able to state the process in either form.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 06/21/07 have been fully considered but they are not persuasive.

Applicant argues that Document '746 discloses the preparation of an aqueous suspension on the pilot plant scale in which sterilized and micronized BDP is placed in suspension firstly by magnetic stirring and then by turbine stirring at 2600 rpm. Applicant continues that "when this process is applied on the industrial scale, the processing times for achieving homogenization are long, and the dispersions obtained do not have satisfactory homogeneity". Applicant also states that in the claimed process no magnetic stirring of the particle containing suspension is conducted, but a vacuum is applied.

The arguments are not commensurate with the scope of claims. In the process of examination claims are given their broadest interpretations, and while they are interpreted in light of the specification, limitations from the specification are not read into the claims. Here, the instant claims are not limited by the scale of production, they use the open language of comprising and the step of magnetic stirring has not been excluded. The process step of vacuuming the liquid is clearly disclosed in the prior art as one of two options.

Applicant, by referring to Table 2 of the instant specification, states that the process disclosed in '746 reference would not produce "finer particles with a narrower and more homogenous particle size distribution". In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., finer particles with narrower and more homogenous particle size distribution) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant makes analogous arguments against the Obviousness Double Patenting rejection because U.S. Patent 6,464,956 is equivalent to '746 reference. Again, the arguments are not commensurate with the scope of claims. Both sets of claims employ the open language of "comprising" and instant claims do not recite any

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limitation that is not taught by the reference claims. Furthermore, Patent '956 discloses that vacuum is one of the two options.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

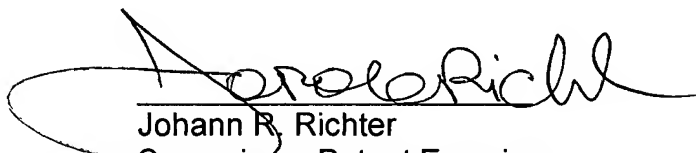
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian
Patent Examiner
September 10, 2007



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